## REMARKS

Claims 1-81 are all the claims pending in the application; claims 2-9, 17-34, 36-47 and 51-81 are withdrawn from consideration; claims 1, 10-16, 35 and 48-50 are pending.

Included herewith are amendments to the claims. Claims 1-81 are canceled; new claims 82-93 are added.

The claims have been amended to limit them to the elected species, namely the CsaE polypeptide. Support for the new claims can be found in the original claims filed with the application and in the specification. For example, new claim 82 corresponds to claim 49, with further support for SEQ ID NO:10 in the specification (see, e.g., page 18, line 4). New claim 83 corresponds to original claim 11. New claim 84 corresponds to original claims 48 and 49. New claim 85 finds support in the specification at page 12, line 27, through page 13, line 26. New claim 86 corresponds to the subject matter of original claim 1. New claims 87-90 correspond to original claims 12-15. New claim 91 finds support in the specification at page 32, lines 24-26. New claims 92 and 93 find support in the specification at page 32, lines 4-11.

No new matter has been added. Entry of the amendment is respectfully requested.

### I. Drawings

At paragraph 5 of the Office Action, the Examiner states that the proposed drawing correction for Figures 2A and 2B has been approved, and that corrected drawings are required to be submitted with the response to the outstanding Office Action.

In response, Applicants include herewith a Submission of Drawings, along with one sheet of drawings containing revised Figures 2A and 2B. In view of this submission, Applicants respectfully request reconsideration and withdrawal of this objection.

**II. Rejection of Claims Under 35 U.S.C. §112**

**A.** At paragraph 7 of the Office Action, claim 16 has been rejected as lacking adequate written description support in the specification as filed. The Examiner states that while the claim has been amended to read on an immunogenic composition comprising a carrier comprising a *csa* operon, the application does not disclose such a carrier.

In view of the cancellation of claim 16, this rejection is moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**B.** At paragraph 8 of the Office Action, claims 1 and 12-16 have been rejected as being indefinite. The Examiner states that while an Applicant is his own lexicographer, a term may not be given a meaning repugnant to the usual meaning of that term. The Examiner points to the term "recombinant product" and states that Applicants use the term in such a manner that it includes the nucleic acid itself or a fragment of itself. Thus, the claims are rejected as being indefinite.

In view of the cancellation of claims 1 and 12-16, this rejection is moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection. Applicants also note that none of the new claims use the term "recombinant product."

**III. Rejection of Claims Under 35 U.S.C. §102**

**A.** At paragraph 10 of the Office Action, the rejection of claims 1, 10-11, 25 and 48-50 under 35 U.S.C. §102(b) as being anticipated by McConnell et al., and separately by Rudin et al., has been maintained.

The Examiner states that both of the references disclose an immunogenic composition comprising the CS4 fimbria as an antigen. With regard to McConnell et al., the Examiner explains that because the entire CS4 proteins was apparently expressed by the microbe, and thus served as the immunogen, the reference inherently discloses an immunogenic

composition comprising the CsaE subunit. With regard to Rudin et al., the Examiner states that this reference teaches the use of isolated CS4 protein as an antigen.

The Examiner concludes that as the application does not identify any distinguishing characteristics between the CS4 fimbria in nature and the recombinant product, the source of the antigen is not deemed pertinent to patentability.

Applicants note that the disclosure of McConnell et al. is limited to the use of strains of *E. coli* that express the CS4 fimbria in the immunization of rabbits, and the isolation of anti-CS4 antibodies (see page 1975, column 1, fourth full paragraph). Further, the disclosure of Rudin et al. is limited to the preparation of isolated CS4 fimbria and their use in the immunization of mice (see page 137, fifth paragraph), and isolation of antibodies that recognize the CS4 fimbria. Thus, both references disclose the use of naturally-occurring CS4 fimbria.

In contrast, in the new claim set presented with the instant amendment, Applicants claim a substantially pure CsaE polypeptide, homologues thereof, and immunogenic compositions comprising the CsaE polypeptide or homologues. As stated in the specification at page 19, last paragraph, "[b]y a 'substantially pure polypeptide' is meant a csa operon encoded protein that has been separated from components that naturally accompany it." Thus, in view of the "substantially pure" language in the claims, Applicants are reciting a CsaE polypeptide free of other naturally-occurring components, such as the CsaB polypeptide. Applicants are therefore not reciting naturally-occurring CS4 fimbria that is disclosed in the two cited references, which is a dimer of CsaB and CsaE.

Furthermore, neither of the two references cited by the Examiner teach the CsaE polypeptide, or the polynucleotide encoding the polypeptide. Nor does either reference teach

that the CS4 fimbria is comprised of two different proteins (CsaB and CsaE), or the separation and purification of the two different proteins.

Applicants further assert that the skilled artisan would not expect that an immunogenic composition comprising substantially purified CsaE protein would induce the same immune response as an immunogenic composition comprising the CS4 protein. Due to differences in the three-dimensional confirmation of substantially purified CsaE protein and the CS4 protein (which is a dimer of CsaB and CsaE), the skilled artisan would expect that different antigenic epitopes would be exposed on the two proteins.

Therefore, it is clear that neither of the references cited by the Examiner teach, or suggest, the substantially pure CsaE polypeptide, or immunogenic compositions comprising the CsaE polypeptide. Accordingly, Applicants assert that none of the claims in the new claim set is anticipated by the references cited by the Examiner, and Applicants respectfully request reconsideration and withdrawal of this rejection.

**B.** At paragraph 11 of the Office Action, the rejection of claims 1, 12-15 and 35 under 35 U.S.C. §102(b), as being anticipated by Cassels et al. (WO 96/38171), has been maintained.

The Examiner states that the claims of the pending application recite an immunogenic composition comprising a recombinant product of a *csa* operon and a carrier (claim 1), and a purified polypeptide sequence expressed from a recombinant *csa* operon (claim 35).

In the prior Office Action, the Examiner had stated that Cassels et al. discloses a CS4 fragment usable as an immunogen, substantially identical to residues 24-60 of SEQ ID NO:4 (CsaB) (see Office Action dated July 30, 2003, page 5, lines 16-17).

The Examiner concludes that as the claims encompass polypeptide fragments such as those of Cassels et al., the claims are anticipated.

In response, Applicants note that the claims have been amended to recite polypeptides and immunogenic compositions based on the CsaE polypeptide. Cassels et al. does not disclose a substantially pure CsaE polypeptide or the amino acid sequence of the CsaE polypeptide or the polynucleotide sequence encoding the CsaE polypeptide. Indeed, as noted by the Examiner, each of the peptides disclosed in Cassels is based on CsaB, not CsaE.

Therefore, as Cassels et al. does not teach each element of the claimed invention, Applicants respectfully request reconsideration and withdrawal of this amendment.

## IV. Rejection of Claims Under 35 U.S.C. §103

At paragraph 14 of the Office Action, the rejection of claims 12-15 as being unpatentable under 35 U.S.C. §103(a) over McConnell et al. in view of Cassels has been maintained.

The Examiner states that the claims are being read as to encompass the immunogenic compositions of claims 12-15 wherein the peptides are those taught by McConnell.

In response, Applicants again note the amendment to the claims, and assert that neither McConnell et al. nor Cassels disclose an immunogenic composition comprising substantially purified CsaE protein.

As discussed above in section **III. A.**, McConnell et al. only discloses the use of naturally-occurring CS4 fimbria. It does not teach or suggest a substantially pure CsaE polypeptide or a immunogenic compositions comprising the CsaE polypeptide.

Furthermore, as explained above in section **III. B.**, Cassels only discloses a fragment of CsaB. It does not teach or suggest the CsaE polypeptide, or any of the related subject matter recited in the claims.

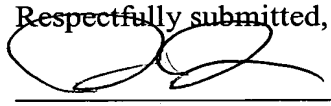
Accordingly, neither McConnell et al. or Cassels, alone or in combination, make obvious the claimed invention. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

## IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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